



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

SonoScape Company Limited  
% Toki Wu  
Yizhe Building, Yuquan Road  
Nanshan, Shenzhen, 518051  
P.R.CHINA

April 28, 2015

Re: K150045

Trade/Device Name: S30/S40 Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: March 3, 2015

Received: March 30, 2015

Dear Toki Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". To the left of the signature, there is a small, faint watermark or logo that appears to be the FDA seal or logo.

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

510(k) Number (*if known*)

K150045

Device Name

S30/S40 Digital Color Doppler Ultrasound System

**Indications for Use (Describe)**

The SonoScape S30/S40 system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Transrectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.

**Type of Use (Select one or both, as applicable)**

Prescription Use (Part 21 CFR 801 Subpart D)  Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## Diagnostic Ultrasound Indications for Use Form

System: SonoScape S30/S40

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic	N	N	N		N	N	Note 1	Notes 2,4
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6,7
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P	N	P	P	Note 1	Notes 2,4
	Cerebral vascular			N					

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: C322 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular								

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI                    Note 4: 3D                    Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: C344 Curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: C345 Curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: C353 Curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: C542 Curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular								

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI                    Note 4: 3D                    Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: C613 Micro-curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: 2P1 Phase Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: 2P2 Phase Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: 3P1 Phase Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

### Transducer: 5P1 Phase Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: 5P2 Phase Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: 8P1 Phase Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: L741 Linear Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: L742 Linear Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents.

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: L743 Linear Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: L752 Linear Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

### Transducer: 10L1 Linear Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: 6V1 Micro-curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

### Transducer: 6V3 Micro-curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: 6V1A Micro-curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: EC9-5 Micro-curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: BCC9-5 Micro-curved Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: BCL10-5 Biplane Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: MPTEE Phased Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: MPTEE mini Phased Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: CWD2.0

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: CWD5.0

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

Transducer: PWD2.0

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Cerebral vascular			N					

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## Diagnostic Ultrasound Indications for Use Form

## Transducer: LAP7 Linear Array

## Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**N = new indication; P = previously cleared by FDA; E = added under this appendix**

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

#### Note 6: Small Organ: breast, thyroid, testes

## Note 7: Elastography

## 510(k) Summary

### 1. Submitter [21 CFR807.92 (a) (1)]

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Date Prepared January 9, 2015

### 2. Device [21 CFR807.92 (a) (2)]

Trade Name: S30/S40 Digital Color Doppler Ultrasound System  
Common Name: Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Classification Panel: Radiology

Device Class: II

### 3. Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate devices within this submission are as follows:

SonoScape S30 Digital Color Doppler Ultrasound System	K132527
SonoScape S40 Digital Color Doppler Ultrasound System	K131213
SonoScape S9 Portable Digital Color Doppler Ultrasound System	K142710

### 4. Device Description [21 CFR 807.92(a) (4)]

This SonoScape S30/S40 Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array with a frequency range of 2.0 MHz to 15.0 MHz.

This system consists of a mobile console with touch screen and keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, 3D/4D.

The subject of this submission is the addition of new indications, new probes and special function to original SonoScape S30 and the addition of S40 model.

New indications      Cerebral Vascular and Laparoscopic.

New probes      Add C345, C613, 2P2, 3P1, 5P2, 8P1, 6V1A, CWD2.0, CWD5.0, PWD2.0 and LAP7 probes.

Special function      Elastography.

Added Model      S40

## **5. Intended Use [21 CFR 807.92(a) (5)]**

The SonoScape S30/S40 system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Transrectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology.

## **6. Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]**

S30/S40 Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate devices:

SonoScape S30 Digital Color Doppler Ultrasound System	K132527
SonoScape S40 Digital Color Doppler Ultrasound System	K131213
SonoScape S9 Portable Digital Color Doppler Ultrasound System	K142710

*Intended Use Comparison:*

Compared with SonoScape S9 (K142710), the Subject Device S30/S40 has the same intended uses.

*Technical Characteristics Comparison:*

The basic and main technical features of the Subject Device S30/S40 are similar to SonoScape S9 (K142710) and the same as the Predicated Device original SonoScape S30 (K132527) and S40 (K131213) separately, including Design, Operation Controls, Display Modes, Measurement Items, Cine Loop and Operating and Storage Condition. For Operation Modes, Elastography is a special Operation Mode for the Subject Device S30/S40, but already employed by many marketed devices and same as the Predicate Device SonoScape S9 (K142710).

The detailed technical features comparison and analysis can be found in **Substantial Equivalence Comparison** and the detailed technical features can be found in **General Device Descriptions** of the submission.

*Probes Comparison:*

Subject device S30/S40 has the similar probes as the predicated device SonoScape S9 (K142710) and original SonoScape S30 (K132527).

**Table 1 Probes Comparison**

Subject device SonoScape S30/S40	Predicate Device SonoScape S9	Remark
C322 Micro-curved Array C344 Curved Array C345 Curved Array C353 Curved Array C542 Curved Array	C322 Micro-curved Array C344 Curved Array C353 Curved Array C542 Curved Array	<b>SE</b> Analysis1
VC6-2 Curved Array	VC6-2 Curved Array	<b>Same</b>
C613 Micro-curved Array	C613 Micro-curved Array	<b>Same</b>
2P2 Phased Array 3P1 Phased Array 5P2 Phased Array 8P1 Phased Array	2P2 Phased Array 3P1 Phased Array 5P2 Phased Array 8P1 Phased Array	<b>Same</b>
L741 Linear Array L742 Linear Array L743 Linear Array L752 Linear Array 10L1 Linear Array	L741 Linear Array L742 Linear Array L743 Linear Array L752 Linear Array 10L1 Linear Array	<b>Same</b>
6V1 Micro-curved Array 6V1A Micro-curved Array	6V1 Micro-curved Array	<b>SE</b> Analysis1

6V3 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array)	6V3 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array)	<b>Same</b>
MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane)	MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane)	<b>Same</b>
CWD2.0, 2.0 MHz CWD5.0, 5.0 MHz PWD2.0, 2.0 MHz	CWD2.0, 2.0 MHz CWD5.0, 5.0 MHz PWD2.0, 2.0 MHz	<b>Same</b>
LAP7, Linear Array	LAP7, Linear Array	<b>Same</b>
<b>Subject device</b> <b>SonoScape S30/S40</b>	<b>Predicate Device</b> <b>Original SonoScape S30</b>	<b>Remark</b>
2P1 Phased Array 5P1 Phased Array	2P1 Phased Array 5P1 Phased Array	<b>Same</b>

### SE Analysis 1:

Compared with the predicate device SonoScape S9 and original SonoScape S30, there are only two new probes (C345 and 6V1A) for the subject device, but no new intended use. And the frequency and performance of C345 and 6V1A probes is the same as C344 and 6V1 probes respectively for predicate device.

Moreover, compared with predicated devices, the subject device (S30/S40) complies with the same regulation and safety standards and has the consistent acoustic output levels. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

### 7. Non-Clinical Tests [21 CFR 807.92(b) (1)]

The S30/S40 Digital Color Doppler Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output.

Laboratory tests (including strain Elastography function) were conducted to verify that the S30/S40 system met all design specifications and the S30/S40 system conformed to applicable medical device standards. The S30/S40 system has been designed and manufactured to meet the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5, ISO10993-10, UD2, and UD3.

**8. Clinical Test [21 CFR 807.92(b) (2)]**

No clinical testing was required.

**9. Substantially Equivalent Conclusions [21 CFR 807.92(b) (3)]**

In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S30/S40 Digital Color Doppler Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.